

ABSTRACT

This invention relates to crystals of whole antibodies and fragments thereof, and formulations and compositions comprising such crystals. More

5 particularly, methods are provided for the crystallization of high concentrations of whole antibodies, and fragments thereof, in large batches, and for the preparation of stabilized whole antibody crystals for use alone, or in dry or slurry  
10 formulations or compositions. This invention also relates to methods for stabilization, storage and delivery of biologically active whole antibody crystals.

The present invention further relates to  
15 methods using whole antibody crystals, antibody fragment crystals, or compositions or formulations comprising such crystals for biomedical applications, including biological delivery to humans and animals. More particularly, highly concentrated whole antibody  
20 or antibody fragment crystal formulations or compositions are useful for delivery of large amounts of antibodies in a small volume to a subject, when and where they are needed. According to one embodiment of this invention, whole antibody crystals or antibody  
25 fragment crystals are used as a carrier-free delivery system which can slowly release active whole antibodies or fragments thereof, to a subject, where and when they are needed. According to an alternate embodiment of this invention, whole antibody crystals or antibody  
30 fragment crystals, or crystal formulations thereof, are encapsulated within a matrix comprising a polymeric carrier to form a composition.

Methods are also provided for preparing stabilized formulations of whole antibody crystals or

antibody fragment crystals using pharmaceutical ingredients or excipients and optionally encapsulating the crystals or crystal formulations in a polymeric carrier to produce compositions and using such protein  
5 crystals for biomedical applications, including delivery of therapeutic proteins and vaccines.